

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO**

BERKEY INTERNATIONAL, LLC,

Plaintiff,

v.

ENVIRONMENTAL PROTECTION  
AGENCY, et al.

Defendants.

Civil No. 3:24-cv-01106-CVR

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR  
PRELIMINARY INJUNCTION**

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This case is straightforward, despite Plaintiff Berkey International LLC's ("Plaintiff" or "Berkey International") efforts to complicate it.<sup>1</sup> EPA can issue Stop, Sale, Use, or Removal Orders ("SSUROs") whenever it has "*reason to believe*" that a pesticide has been or is intended to be distributed or sold in violation of the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"). 7 U.S.C. § 136k(a). EPA learned that certain Berkey water filtration products ("Berkey Products") manufactured or assembled by Plaintiff incorporated anti-microbial silver and were being sold with labels claiming that they could remove viruses and pathogens from water sources. This provided EPA with "reason to believe" that the sale and distribution of Berkey Products violated FIFRA. EPA therefore properly issued a SSURO to Plaintiff on May 8, 2023. Ex. 1.

Plaintiff waited more than 300 days after receiving its SSURO before seeking "emergency" relief. Plaintiff now not only requests an order setting aside the SSURO that it received, but further wrongfully attempts to set aside SSUROs issued to non-parties and enjoin EPA from issuing SSUROs related to Berkey Products to anyone again.

Plaintiff has standing to bring claims related only to the SSURO it received. As to that, Plaintiff's motion for emergency relief fails. Plaintiff cannot show a likelihood of success on the merits because its own evidence demonstrates that EPA issued the SSURO based on long-standing and well-publicized interpretations of FIFRA and EPA's regulations. Plaintiff also fails to demonstrate irreparable harm; any conclusory allegations of economic harm are attributable to other factors, including a recently settled widely publicized class-action lawsuit alleging that

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<sup>1</sup> This brief addresses only Plaintiff's motion for preliminary injunction and to demonstrate why injunctive relief is inappropriate. Defendants reserve the right to assert all defenses afforded in the Federal Rules of Civil Procedure in any future response to Plaintiff's Complaint, including, but not limited to, those available under Rule 12(b).

Berkey Products do not perform as advertised.<sup>2</sup> Finally, Plaintiff cannot show that the public interest or balance of the equities tilts in its favor because the public interest in regulating pesticide consumer products predominates. Plaintiff thus meets no element of the test. *See Winter v. NRDC*, 555 U.S. 7, 20 (2008). The Court should deny its motion.

## **Background**

### **A. Legal Background**

FIFRA governs the production, sale, distribution, and use of pesticides, which include “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u).<sup>3</sup> Longstanding EPA regulations define when a “substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration.” 40 C.F.R. § 152.15; *infra* at 3. FIFRA makes it unlawful, with some exceptions, for any “person in any State [to] distribute or sell to any person any pesticide that is not registered” under the Act. 7 U.S.C. § 136a(a); *id.* § 136j(a)(1)(A).

EPA also regulates “devices” under FIFRA. In general, a “device” is an “instrument or contrivance . . . intended for trapping, destroying, repelling, or mitigating any pest . . .,” subject to certain exceptions not relevant here. 7 U.S.C. § 136(h). Devices are not subject to FIFRA’s product-specific, pre-sale registration requirements. That said, devices are subject to various requirements, including that they must be produced at a registered establishment and must not be

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<sup>2</sup> *See Farrell et al. v. New Millennium Concepts, Ltd*, Case No. 3:22-cv-00728, (N. D. Tex.) (alleging Berkey Products “fail to ‘purify’ water and fail to eliminate or dramatically reduce contaminants to the extent advertised.” In February 2024, the case settled via a private settlement agreement and the parties stipulated to dismissal of the case. 3:22-cv-00728 ECF No. 78, ECF No. 80.

<sup>3</sup> Subject to exceptions not relevant here, a “pest” is “[a]ny fungus, bacterium, virus, prion, or other microorganism” that is “deleterious to man or the environment.” 40 C.F.R. § 152.5.



“misbranded.” 40 C.F.R. § 152.500(b); *see also* 7 U.S.C. §§ 136(q)(1), 136e. Since 1975, EPA has interpreted “devices” to include water filters, with a critical exception: “*those containing substances or mixtures of substances which are pesticides.*” 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added). If “a product ... incorporates a substance or mixture of substances intended to ... destroy ... or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3.” U.S. EPA, *Pesticide Registration Manual: Chapter 13 - Devices*, Pesticide Registration, (last updated Oct. 23, 2023); *see also* Pest Control Devices and Device Producers, Consolidation, and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976) (same).<sup>4</sup>

EPA’s regulations include the treated article exemption which exempts articles that would otherwise require registration because they incorporate a pesticidal substance if the pesticide is intended only “to protect” the articles themselves, but only if that pesticide “is registered for such use.” 40 C.F.R. § 152.25(a). Under EPA’s longstanding interpretation, “articles ... bearing implied or explicit public health claims against human pathogens” generally do not qualify for this exemption because such claims indicate that the treating pesticide is intended for purposes other than protecting the article. *See* U.S. EPA, Pesticide Registration (PR) Notice 2000-1, Notice to Manufacturers, Formulators, Producers, and Registrants of Pesticide Products (Mar. 6, 2000).<sup>5</sup> Public health claims include, *inter alia*, claims “for control of specific microorganisms or classes of microorganisms that are ... infectious or pathogenic”; claims “for the product as a sterilant, disinfectant, virucide or sanitizer”; or claims “that the product will beneficially impact or affect

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<sup>4</sup> Available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices> (last visited Apr. 16, 2024).

<sup>5</sup> Available at <https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides> (last visited Apr. 16, 2024).

public health by pesticidal means at the site of use or in the environment in which applied.” *Id.* at 2-3.

EPA “is charged with choosing the means by which to enforce and achieve the goals of FIFRA.” *Sultan Chemists, Inc. v. EPA*, 281 F.3d 73, 83 (3d Cir. 2002). One enforcement option is to issue SSUROs “[w]henever . . . there is reason to believe . . . that [a] pesticide or device has been or is intended to be distributed or sold in violation of any” provision of FIFRA. 7 U.S.C. § 136k(a). A SSURO prohibits the sale, use, or removal of a pesticide “except in accordance with the provisions of the order.” *Id.*

## **B. Factual Background**

The United States first registered products containing antimicrobial silver as a pesticide in 1954.<sup>6</sup> Ingestion of silver may cause, among other things, breathing problems, abdominal pain, and rashes, swelling, and skin inflammation in humans and animals.<sup>7</sup>

Over 125 products containing silver are registered as pesticides with EPA.<sup>8</sup> Among other uses, products containing silver are registered under FIFRA to inhibit the growth of bacteria within the filter unit of water filter systems designed to remove objectionable taste, odors, and color from municipally treated tap water.<sup>9</sup>

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<sup>6</sup> U.S. EPA, [R.E.D. Facts Silver](#) at 2, June 1993, (last viewed on Apr. 16, 2024).

<sup>7</sup> *Id.* at 2-4.

<sup>8</sup> U.S. EPA, [Chemical Name: Silver](#), (last viewed on Apr. 16, 2024).

<sup>9</sup> *Id.*; see also FIFRA registrations for an example of a water filter that contains silver: [EPA Reg. No. 35900-3](#) (last viewed on Apr. 16, 2024).

Berkey International LLC is a Puerto Rican limited liability company founded in 2015. Compl. ¶ 1.<sup>10</sup> It manufactures a variety of Berkey Products. Compl. ¶ 19; Ex. 1 ¶ 28.

Following an investigation, EPA determined that the Berkey Products distributed by Plaintiff contain antimicrobial silver and are being sold with labeling claiming that the Products remove pests that threaten public health from various water sources. Ex. 1 at 3-5. EPA therefore issued a SSURO to Plaintiff.<sup>11</sup>

To date, to the best of EPA's knowledge, the violative products still contain silver, are being advertised for pesticidal purposes,<sup>12</sup> are not registered with EPA, and do not meet the labeling requirements in FIFRA for either pesticides or devices. Plaintiff has not yet shown how any of the offending products could meet the treated article exemption.<sup>13</sup>

### Legal Standards

#### A. Preliminary Injunction Standard

The First Circuit has repeatedly cautioned that a “preliminary injunction is an extraordinary and drastic remedy that is never awarded as of right.” *Peoples Fed. Sav. Bank v. People's United Bank*, 672 F.3d 1, 8-9 (1st Cir. 2012) (citations omitted). The moving party must demonstrate that

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<sup>10</sup> Government of Puerto Rico, Department of State, Corporation Information, Berkey International LLC, <https://rceweb.estado.pr.gov/en/entity-information/?c=365440-1511> (last viewed on Apr. 16, 2024).

<sup>11</sup> 7 U.S.C. § 136k; U.S. EPA, *FIFRA Enforcement Response Policy*, December 2009, <https://www.epa.gov/sites/default/files/documents/fifra-erp1209.pdf> (last viewed on Apr. 16, 2024).

<sup>12</sup> *What does Berkey Water Filter Remove? Lab Test Results*, App. at 1-39; available at [https://theberkey.com/pages/test-result?\\_pos=1&\\_sid=512c81191&\\_ss=r](https://theberkey.com/pages/test-result?_pos=1&_sid=512c81191&_ss=r) (last viewed on Apr. 16, 2024) (“The Berkey filters can be classified as water purifiers because they remove 99.9999999% of pathogenic bacteria and 99.999% of viruses, significantly exceeding the standard.”).

(1) “he is likely to succeed on the merits”; (2) “he is likely to suffer irreparable harm in the absence of preliminary relief”; (3) “the balance of equities tips in his favor”; and (4) “an injunction is in the public interest.” *Winter*, 555 U.S. at 20.

## **B. Merits Standard**

This Court has jurisdiction under FIFRA to review “final actions” of the EPA Administrator other than those actions issued “following a public hearing.” 7 U.S.C. § 136n(a), (b). FIFRA does not provide a standard of review; thus, courts use the APA standard. *See Defs. of Wildlife v. Adm’r, E.P.A.*, 882 F.2d 1294, 1302 (8th Cir. 1989) (citation omitted) (FIFRA judicial review is conducted “in accordance with the law generally applicable to administrative procedure”).

Under that standard, the party challenging an agency action must show that the action was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *NRDC, Inc. v. U.S. E.P.A.*, 824 F.2d 1258, 1267 (1st Cir. 1987). The court’s review is limited to the administrative record compiled by the agency and “not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Review is deferential and narrow, and a court may not substitute its judgment for that of the agency. *See Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The court considers only whether the agency’s “decision was based on a consideration of the relevant factors and whether the agency made a clear error in judgment.” *Airport Impact Relief, Inc. v. Wykle*, 192 F.3d 197, 202–03 (1st Cir. 1999) (collecting cases). Particular deference is given to an agency regarding technical matters in its area of expertise. *City of Taunton v. U. S. E.P.A.*, 895 F.3d 120, 126 (1st Cir. 2018) (citing *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983)); *see also Upper Blackstone Water Pollution Abatement Dist. v. U.S. E.P.A.*, 690 F.3d 9, 20–21 (1st Cir. 2012)).

## Argument and Authorities

### A. Plaintiff is Unlikely to Succeed on the Merits.

#### 1. Plaintiff lacks standing to challenge SSUROs issued to non-parties.

Plaintiff's motion begins with a request that this Court stop enforcement of all "SSUROs," plural, and continues with requests for relief on behalf of third parties in addition to itself. Mot. at 1; *see also, e.g.*, Mot at 4; 8 ("EPA cannot point to any pesticidal claim made by the SSURO recipients when issuing their SSUROs"; "Each day the SSUROs are in place Berkey is harmed"); Compl. ¶¶ 54, 61, 62, 63, 64 & 65 (including allegations concerning SSUROs issued to third parties). For purposes of this motion only, we assume that Plaintiff has Article III standing to request injunctive relief related to the SSURO issued to it on May 8, 2023. Plaintiff does not, however, have standing to bring claims on behalf of non-parties. *Singleton v. Wulff*, 428 U.S. 106, 113 (1976).

"Federal courts must hesitate before resolving a controversy ... on the basis of the rights of third persons not parties to the litigation." *Singleton*, 428 U.S. at 113; *see also Kowalski v. Tesmer*, 543 U.S. 125, 129-130 (2004) (assuming a litigant's Article III standing but dismissing their claims for lack of third-party standing). Plaintiff offers nothing that could overcome this hesitation. Indeed, in an earlier-filed suit that Plaintiff's counsel describes as "effectively the same case" as this one, Norred Decl., ECF No. 36 at 4, the U.S. District Court for the Northern District of Texas dismissed an attack on SSUROs issued to non-parties for lack of third-party standing.<sup>14</sup> *See also* ECF No. 36 at 2 ("This case was filed because the appeal of the currently dismissed '826

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<sup>14</sup> *James Shepherd, et al. v. Regan, et al.*, Case No. 4:23-cv-00826-P (N.D. Tex.) ("*Shepherd* lawsuit"). The District Court dismissed the *Shepherd* lawsuit because the Plaintiffs there lacked Article III and third-party standing. *Id.*, ECF No. 32 (Ex. 2). The Plaintiffs in that case appealed the District Court's decision in the Fifth Circuit. Case No. 23-11189. The appeal is pending.

case will take a substantial amount of time”). Plaintiff has no more right to assert claims on behalf of non-party SSURO recipients here. The only claim properly before the court is Berkey International’s challenge to the SSURO it received on May 8, 2023.

## **2. EPA reasonably issued a SSURO to Berkey International.**

Plaintiff has not made more than a perfunctory attempt to provide a basis for injunctive relief related to the SSURO it received. *See Muniz v. Rovira*, 373 F.3d 1, 8 (1st Cir. 2004) (confirming “that issues raised perfunctorily, without developed argumentation, will not be considered”); *see also J. Cajigas & Assocs., PSC v. Municipality of Aguada*, No. 13-1359 (JAF), 2014 WL 320653, at \*2 (D.P.R. Jan. 29, 2014) (“Perfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are deemed waived.”). For that reason alone, this Court should deny Plaintiff’s motion for preliminary injunction.

Even if the Court considers Plaintiff’s arguments on the merits, Plaintiff is unlikely to succeed. EPA may issue SSUROs whenever it has “*reason to believe*” that the recipient has distributed or sold, or intends to distribute or sell, a pesticide or device “in violation of any” provision of FIFRA. 7 U.S.C. § 136k(a) (emphasis added). A pesticide includes “any substance[(s)] ... intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u); *see also* 40 C.F.R. § 152.15. Berkey Products were marketed with claims that they “prevent[ed], destroy[ed], or mitigate[ed],” 7 U.S.C. § 136(u); *see also* 40 C.F.R. § 152.15, viruses and pathogenic bacteria, and they contain antimicrobial silver, an active ingredient in pesticides that have been registered for use on water filters for the pesticidal purpose of eliminating microbes that can grow on the filter, *see supra* at p. 5. EPA therefore had “reason to believe” that Berkey Products were pesticides intended for a pesticidal purpose, that the product had been distributed and sold, and that Berkey intended to distribute and sell more of the product. And because Berkey

Products are not registered under FIFRA, EPA had reason to believe that their continued sale violated FIFRA's bar on the sale of unregistered pesticides and the applicable FIFRA labeling requirements for both pesticides and devices. EPA therefore acted reasonably in issuing a SSURO to Plaintiff.

### **3. Plaintiff's counterarguments are meritless.**

Plaintiff insists that its SSURO was based on a new rule that EPA failed to issue through notice and comment procedures (Counts 1 & 4.i); was inconsistent with FIFRA's definition of "pesticide" (Counts 2 & 4.ii); rested on an unconstitutionally vague statutory definition of "pesticide" (Count 3); deprived Plaintiff of liberty or property without due process (Counts 4.i (again) & 5); and violated a constitutional prohibition on regulating water filters (Count 6). None of this withstands scrutiny. To issue a SSURO to Berkey International, EPA applied long-extant law to the facts contained in the administrative record. FIFRA's definition of "pesticide," cited above, has been in place for 52 years. *See* Pub. L. No. 92-516, 86 Stat. 973 (Oct. 21, 1972). EPA's regulations defining "pesticidal purpose" have been in place for 36 years. And for decades, EPA has warned: (1) that products, including water filters, that function through the incorporation of pesticides are pesticides under FIFRA; and (2) that, as a general rule, the treated article exemption from otherwise applicable pesticide registration requirements does not apply to products that make broad public health claims, which go beyond protecting the article itself. *See supra* pp. X-X. Against this backdrop, Plaintiff's complaints about unfair surprise ring hollow.

Plaintiff gets no further by insisting that FIFRA's definition of "pesticide" is unfairly vague (Count 3). A statute will withstand a void-for-vagueness challenge if it "give[s] a person of ordinary intelligence fair notice," using "language that the common world will understand." *United States v. Hussein*, 351 F.3d 9, 13 (1st Cir. 2003) (internal quotation marks omitted). As

relevant here, FIFRA defines a pesticide as “any substance ... intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u). Any reasonable person would understand that definition to include a product that contains silver used as an antimicrobial agent and advertised as removing pests from public water.

The same straight-forward reading of statutory text also rebuts Plaintiff’s assertion that the challenged SSURO deviated from FIFRA’s statutory definition of pesticide (Counts 2 & 4.ii). Plaintiff appears to argue, based on selectively quoted and ambiguous legislative history, that EPA expanded the definition of pesticide to issue SSUROs related to Berkey Products. Compl. ¶¶ 136-39. Plaintiff’s assertion is inaccurate as EPA has used the same definition for decades, *see supra* pp. 2-3 and “legislative history is not the law.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814 (2019).

Plaintiff is no more likely to succeed on its Due Process Clause claim (Count 5), which merely rehashes arguments about EPA’s alleged failure to follow notice and comment procedures before issuing a new rule. Compl. ¶¶ 144-50. Those arguments fail because EPA has not issued a new rule. Contrary to Plaintiff’s assertions, EPA properly used its enforcement authority under section 13 of FIFRA to issue a SSURO to it. *See* 7 U.S.C. § 136k(a). Plaintiff also fails to identify a constitutionally protected liberty or property interest that would trigger due process. *See Harper v. Rettig*, 675 F. Supp. 3d 190, 206 (D.N.H. 2023) (“Absent a protectible liberty or property interest, the protections of procedural due process do not attach.”) (internal quotation marks omitted). The only deprivations that Plaintiff alleges concern its “private interest to be free of wrongful interference in the operations of its business” and “damage to its professional reputation.” Compl. ¶ 149. But “business in the sense of the activity of doing business, or the activity of making a profit is not property” and thus is not a property interest protected by the Due



Process Clause. *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 675 (1999). If Plaintiff has a liberty interest in selling or distributing water filters, that interest “remains intact” because the SSURO limits but— does not prohibit—Plaintiff from selling filters. *Adams v. City of Harahan*, 95 F.4th 908, 916 (5th Cir. 2024) (A “plaintiff’s liberty interest in pursuing a specific profession is only violated if he has been completely prevented from working in that field.”). And reputational harm, by itself, cannot support a due process claim. *Paul v. Davis*, 424 U.S. 693, 701 (1976).<sup>15</sup>

For all these reasons, Plaintiff is unlikely to succeed on the merits of its claims. Plaintiff’s motion for preliminary injunction should therefore be denied.

**B. Plaintiff has Failed to Demonstrate Irreparable Harm.**

Plaintiff improperly attempts to equate “irreparable harm” with “injury-in-fact.” ECF No. 1-1 at 8.<sup>16</sup> Injury-in-fact is a relatively low bar that is separate from irreparable harm. *See O’Neil v. Canton Police Dep’t*, No. 23-cv-12685, 2023 WL 7462523, at \*\*3, 6 (D. Mass. Nov. 10, 2023) (plaintiffs had met the “‘extremely low bar’” to show injury-in-fact to establish standing but failed to show irreparable harm necessary for injunctive relief). Irreparable harm requires “an actual, viable, presently existing threat of *serious* harm” that Plaintiff will suffer before a decision on the merits and that cannot be remedied absent an injunction. *Sierra Club v. Larson*, 769 F. Supp. 420,

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<sup>15</sup> Count 6 asserts that the Ninth and Tenth Amendments imply “rights to filter water.” This claim is unmoored from constitutional text or precedent. No such right exists. And even James Shepherd and NMCL conceded in filings in the U.S. District Court for the Northern District of Texas that a similar claim was “unlikely to succeed” because of “a failure of previous courts to appreciate the Ninth Amendment.” Pls.’ Reply, *Shepherd, et al. v. Regan, et al.*, 4:23-cv-826 (N.D. Tex. Sep. 5, 2023), ECF No. 20 at 9, n.6.

<sup>16</sup> The cases Plaintiff cites address standing, not preliminary injunctive relief.

422 (D. Mass. 1991) (emphasis added); *see also Estancias de Cerro Mar, Inc. v. P. R. Aqueduct & Sewer Auth.*, No. 20-1664 (CVR), 2024 WL 263037, at \*4 (D.P.R. Jan. 23, 2024).

Plaintiff asserts that the SSURO caused irreparable harm because it stopped Berkey International's business operations. ECF No. 1-1 at 8. The SSURO, however, only ordered Plaintiff not to sell products other than in accordance with its terms. ECF No. 1-3 at 68. This may be an injury in fact, but it is not irreparable harm. Further, as explained below, economic loss is not irreparable harm absent evidence of a risk to the very existence of the movant's business. No such demonstration has been made here.

**1. Plaintiff's unsupported claims of economic loss are insufficient to establish irreparable harm.**

As a threshold matter, Plaintiff's lengthy delay before filing suit strongly suggests that any harm Plaintiff has experienced or will experience is not irreparable. *See Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 163 (1st Cir. 2004); *La Simple Co., Ltd. v. SLP Enters.*, No. 21-10058, 2021 WL 1648762, at \*8 (D. Mass Apr. 27, 2021). Had Plaintiff filed suit in May 2023, this case could already have been decided on the merits. In such circumstances, there is a strong equitable presumption against granting a preliminary injunction. *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 31 (D.D.C. 2006); *see also* 11A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice & Procedure* § 2948.1, at 149 (2d ed. 1995) (“[I]f a trial on the merits can be conducted before the injury would occur there is no need for interlocutory relief.”).

Beyond that, claims of economic loss are typically insufficient to establish irreparable harm. *See Estancias de Cerro Mar*, 2024 WL 263037, at \*3. This is true even if alleged financial losses will not be recoverable. *See Biovail Corp. v. FDA*, 519 F. Supp. 2d 39, 49 (D.D.C. 2007). “The only exception may be when losses are so large that they may be irreparable, as when the potential economic loss is so great as to threaten the existence of the movant's business.” *Tropical*

*Chill Corp. v. Pierluisi Urrutia*, No. 21-1411 (RAM-MEL), 2022 WL 2374976, at \*27 (D.P.R. Jan. 17, 2022) (internal quotation marks omitted).

**a. Plaintiff's claims of lost sales and market share do not demonstrate irreparable harm.**

The only specific allegation of Berkey International's lost sales is that it "has \$38,800,000 in wholesale inventory that it is unable to manufacture and sell[.]" ECF No. 1-1 at 10. Plaintiff offers no evidence to substantiate this claim, but, even assuming it is true, courts are reluctant to find that claims of competitive loss in the marketplace constitute irreparable harm, especially where, as here, Plaintiff has failed to explain why it could not regain these competitive losses. *See Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10, 22-23 (D.D.C. 2009); *Biovail*, 519 F. Supp. 2d at 49.

Plaintiff cites *Feinerman v. Bernardi*, 558 F. Supp. 2d 36 (D.D.C. 2008), for the proposition that, because sovereign immunity would bar it from suing the United States for damages, any loss of income at all is *per se* irreparable harm. However, "this cannot be the rule because every action claiming economic loss caused by the government would meet the standard." *Mylan Pharmaceuticals, Inc. v. Sebelius*, 856 F. Supp. 2d 196, 216 (D.D.C. 2012). Thus, *Feinerman* "goes too far and the inability to recover economic losses can more accurately be considered as a factor in determining whether the movant has shown irreparable harm." *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 49 (D.D.C. 2014).

Even if the rule in *Feinerman* were applied here, it is distinguishable. In *Feinerman*, the plaintiff was threatened with the permanent loss of 40% of his customer base. 558 F. Supp. 2d at 50-51; *see also ConverDyn*, 68 F. Supp. 3d at 49 (discussing *Feinerman*). Here, by contrast, Plaintiff's inventory may represent delayed or deferred sales, not permanently lost sales. Plaintiff thus has not shown any permanent loss. *See Alphapointe v. Dep't of Veterans Affairs*, 416 F. Supp.

3d 1, 9 (D.D.C. 2019) (rejecting *Feinerman* and holding that short-term temporary losses were “speculative and theoretical” and did not represent irreparable harm).

Plaintiff’s other claims of lost sales and market share are that Berkey Products *generally* have lost ground to competitors, and, therefore, other unidentified sellers (not Plaintiff) have lost sales and market share. As explained below, alleged injuries to others do not establish irreparable harm to Berkey International. Even if third-party injuries could be considered, Plaintiff has failed to make its case. For example, Plaintiff claims that Berkey Products have lost sales to competitors on Amazon. In support, Plaintiff offers Exhibit B-17, which purports to compare sales on Amazon of the “Big Berkey” and “equivalent unit sales” (which is not defined) of four unidentified competitors from the first half of 2022 and 2023. Exhibit B-17 is inadmissible, does not show what Plaintiff claims it shows, and suffers from other flaws.<sup>17</sup> Regardless, to establish irreparable harm Plaintiff must demonstrate a sufficient causal connection between the alleged irreparable harm and the activity to be enjoined. *See Puerto Rico v. OPG Tech., Inc.*, Civil No. 15-3125, 2016 WL 5724807, at \*18 (D.P.R. Sept. 6, 2016), *report and recommendation adopted*, 2016 WL 571973 (Oct. 1, 2016). Plaintiff offers no evidence that it sells (or ever sold) Berkey Products on Amazon. Without such evidence, there is no causal link between an alleged decline in Amazon sales and any loss of sales or market share by Plaintiff.<sup>18</sup> Therefore, the alleged decline in sales

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<sup>17</sup> Exhibit B-17 lacks a proper foundation and is an impermissible lay opinion and is therefore inadmissible. Even if admissible, all it shows is that between January 2023 (one month after the first Berkey-related SSURO was issued to another party) and June 2023 (one month after a SSURO was issued to Plaintiff), sales of the Big Berkey fluctuated slightly up and down but did not vary significantly from 2022 sales (except for a huge *increase* in February 2023). And competitors’ sales did not increase as sales of the Big Berkey declined; they stayed the same. This does not support the conclusion that the issuance of the SSUROs “caused a massive loss” of anyone’s market share to competitor filtration systems. For the same reasons, Plaintiff’s Exhibit B-15 is also inadmissible for the same reasons.

<sup>18</sup> Plaintiff alleges in its Complaint and in the Shepherd Declaration that, in June 2023, Amazon “restricted” sales of Berkey Products. ECF No. 1, ¶ 69; ECF No. 1-2, ¶ 28. The cited sources do

on Amazon does not demonstrate that Plaintiff has suffered or will suffer irreparable harm.<sup>19</sup>

This should end any consideration of retail sales on Amazon (or other platforms). However, to the extent the Court considers these allegations, it should be noted that Plaintiff has made no attempt to account for any of the other, more likely causes for any decline in sales on Amazon (or elsewhere). These include a July 2022 article on the New York Times' Wirecutter criticizing and declining to recommend the "Big Berkey."<sup>20</sup> A quick Internet search turns up numerous additional references to, and discussions about, the class action lawsuit against New Millenium Concepts Ltd. ("NMCL"),<sup>21</sup> in which the plaintiffs claimed that Berkey Products do not work as advertised. NMCL thought this commentary was so significant that it published written responses. *See* Pl.'s. Exs. A-5 (response to Wirecutter article); A-3 (response to class action lawsuit), B-19 (same). These and other criticisms of Berkey Products<sup>22</sup> have far greater

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not say anything of the kind, and Plaintiff provides no details concerning this alleged "restriction." Berkey Products, including new water filtration devices and replacement filters, appear to still be available for sale on Amazon and other online platforms. *See* [Big Berkey on Amazon](#); [Black Berkey replacement filters on Amazon](#); [Berkey Products on eBay](#) (last viewed on Apr. 16, 2024).

<sup>19</sup> Plaintiff also complains about counterfeit products. *See* ECF No. 1-1 at 10. But Plaintiff has offered no evidence that the issuance of the SSUROs resulted in an increase in counterfeit products, that any hypothesized increase caused a distinct harm to Plaintiff, or that any such harm cannot be remedied; indeed, legal remedies are available for counterfeiting, as Plaintiff recognizes in its Motion. *Id.*

<sup>20</sup> Tim Hefferman, *The Big Berkey Water Filter: Uncertified and Inconvenient*, N.Y. TIMES WIRECUTTER (July 22, 2022), App. 40-63, available at <https://www.nytimes.com/wirecutter/reviews/big-berkey-water-filter-system/> (last viewed on Apr. 16, 2024).

<sup>21</sup> *See, e.g.,* u/Ecstatic-Fun-2390, Do not order from berkeywaterfilter.com, r/Berkey, [https://www.reddit.com/r/Berkey/comments/zmu6el/do\\_not\\_order\\_from\\_berkeywaterfiltercom/](https://www.reddit.com/r/Berkey/comments/zmu6el/do_not_order_from_berkeywaterfiltercom/) (last visited Apr. 16, 2024); SR, Berkey Class Action Lawsuit, [Comment to Travel Berkey Gravity-Fed Water Filter with 2 Black Berkey Elements](#) (last viewed on Apr. 16, 2024).

<sup>22</sup> For example, Berkey water filters cannot be sold in California or Iowa because they are not NMF/ANSI certified (a third-party certification that they comply with National Standards for Water Treatment Systems). There are numerous references on the internet suggesting that Berkey

public visibility on the Internet, are more easily understood, and are more readily available to consumers, than the SSURO issued to Berkey International (or the other SSUROs).

**b. Plaintiff's other claims of economic loss are not irreparable harm.**

Plaintiff alleges that, because of the SSUROs, its storage costs are about \$68,000 per month. ECF No. 1-1 at 10. No supporting evidence or additional details are provided to establish these charges are anything other than ordinary business expenses. Plaintiff also alleges that it has a contract with the government of Puerto Rico that requires “maintenance of a certain number [sic] local employees in Puerto Rico,” that these jobs have been lost, and that plaintiff is “in jeopardy with [sic] defaulting on its agreement with Puerto Rico.” ECF No. 1–1 at 9. The contract is not provided nor are any other details about its terms. Plaintiff does not allege any specific harm that will result if it defaults on its contract, other than having to hire and train new employees. And it does not allege, much less demonstrate, that a future default is certain, merely that it is possible. This is not “actual and imminent” harm sufficient to support an injunction. *See Estancias de Cerro Mar*, 2024 WL 263037, at \*4 (movant must demonstrate an injury that is “actual and imminent.”).<sup>23</sup>

**2. Plaintiff cannot establish irreparable harm based on alleged injuries to non-parties.**

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Products are “banned” in these states and/or should be avoided because they lack independent certification. *See* Eva Hagen, [Here's Why Berkey Water Filters Are Banned in California](#), greenmatters (July 12, 2023 9:42 A.M. ET),<sup>2</sup> (last viewed on Apr. 16, 2024).

<sup>23</sup> Plaintiff does not allege in its Motion that either its storage costs or the potential default on its contract threatens the viability of its business. James Shepherd asserts in his declaration, however, that either of these may force Plaintiff out of business by the time this case is finally decided, which he estimates will be in about a year. ECF No. 1-2 ¶¶ 60-61. As noted above, this case could have already been decided had Plaintiff filed suit promptly. Therefore, the possibility that these losses may drive Plaintiff out of business in another year, even if true, does not warrant the issuance of an injunction.

Plaintiff's claims of lost sales on Amazon (or other platforms) are, even if true, claims of harms to unidentified others, not Plaintiff. In addition, Plaintiff alleges that its licensors—the owners of the intellectual property associated with Berkey Products—have been deprived of the royalties they would otherwise have received from Plaintiff's sales, ECF No. 1-1 at 12, and that an unidentified vendor of Berkey International was forced to lay off skilled workers, *id.* at 9. Plaintiff speculates that consumers may be harmed by using “knock off” filters or counterfeit filters. *Id.* at 10. And Plaintiff's Exhibit B-14 contains email traffic in which French distributors of Berkey Products claim harm from statements made in France about the SSUROs.<sup>24</sup>

Even assuming that these claims are true, Plaintiff cannot establish that it will suffer irreparable harm based on injuries to non-parties. *See Winter*, 555 U.S. at 20 (“A plaintiff seeking a preliminary injunction must establish that *he* is likely . . . to suffer irreparable harm in the absence of preliminary relief.”) (emphasis added); *see also Morice v. Hosp. Serv. Dist. # 3*, No. 18-7945, 2019 WL 1517954, at \*7 (E.D. La. Apr. 8, 2019) (“Dr. Morice lacks standing to seek injunctive relief for harm that will occur to others, even to others who would allegedly benefit from such injunctive relief.”).

**1. Plaintiff's unsupported claims of loss of reputation and goodwill do not establish irreparable harm.**

Plaintiff alleges harm to reputation, harm to the “Berkey brand,” and loss of goodwill but provides no specifics and no supporting evidence. ECF No. 1-1 at 9, 11. Courts are often and rightfully reluctant to accept claims of reputational damage, agreeing that the harm is sufficiently irreparable only when it is “pervasive and certain to occur.” *Tex. Marine &*

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<sup>24</sup> These complaints are not that the SSUROs themselves are causing harm but that French competitors of the French Berkey distributors are misrepresenting the nature and effect of the SSUROs. The remedy is legal action against those making the misrepresentations, not lifting the SSUROs.

*Brokerage, Inc. v. Bennington Marine, LLC*, No. 1:12-CV-397, 2012 WL 12888827, at \*5 (E.D. Tex. Oct. 17, 2012), *report and recommendation adopted*, No. 1:12-CV-397, 2012 WL 12892168 (E.D. Tex. Nov. 9, 2012).

Plaintiff's arguments are about Berkey Products generally. It has offered no evidence that harm to Berkey International's reputation, brand, or goodwill in particular is likely to occur. And even if the Court could consider Plaintiff's allegations of harm to the "Berkey brand," Plaintiff has failed to show that such harm would not be due to things like the New York Times negative review, the class action lawsuit, or the perception that Berkey Products are banned in California, all of which have a higher public profile and visibility than the SSURO.

**C. The Balance of the Equities and the Public Interest Weigh Against an Injunction.**

If the Court finds that Plaintiff has failed to demonstrate either a likelihood of success on the merits or irreparable harm, Plaintiff's Motion can be denied without further inquiry. *See New Comm. Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002) (likelihood of success on the merits); *Pub. Serv. Co. of N.H. v. Town of West Newbury*, 835 F.2d 380, 383 (1st Cir. 1987) (irreparable harm). However, the other factors also favor denial of injunctive relief. Where, as here, the opposing party is the government, the two remaining factors, the balance of equities and the public interest, are merged into a single inquiry. *See Nken v. Holder*, 556 U.S. 418, 435 (2009). Plaintiff cites two public interest factors that it claims support temporary equitable relief: (1) EPA's alleged change in its position as to whether registration is required for Berkey Products; and (2) the claim that, if Berkey Products cannot be purchased, consumers will be forced to rely on inferior imitations. ECF No. 1-1 at 13-14. Neither of these supports injunctive relief.<sup>25</sup>

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<sup>25</sup> Plaintiff also reasserts its claims of economic loss, but this is a not public interest factor.



**1. EPA did not change its position.**

Plaintiff does not dispute that antimicrobial silver is in Berkey filters, *see, e.g.*, ECF No. 1, ¶¶37, 39; ECF No. 1-2 ¶ 55, or that Berkey filters have been making pesticidal claims for “decades,” ECF No. 1-1 at 13. This alone was enough for EPA to have reason to believe, when the SSURO was issued, that Berkey filters are within EPA’s FIFRA jurisdiction (as either a pesticide or a device), even if, as Plaintiff now contends, the silver is used only to preserve the integrity of the filter itself. *See supra* at 5. And under either theory of FIFRA jurisdiction, EPA identified FIFRA violations for these products. At the time it issued the SSUROs, the facts before EPA indicated that these products were unregistered pesticides because the filters contained a substance with known antimicrobial properties—silver—and made pesticidal claims. This is consistent with EPA’s decades-long position on such products. Thus, EPA did not change its position on these types of products in issuing the SSURO to Berkey International. Rather, Plaintiff misunderstands—or simply disagrees with—EPA’s position.

To the extent that Plaintiff believes that additional facts unavailable to EPA at the time it issued the SSUROs should alter EPA’s understanding of its jurisdiction over these products, EPA was (and continues to be) willing to consider those facts in considering how to resolve the SSURO. But given the harm that can be caused by the ingestion of silver, *see supra* at 4, and the FIFRA violations under any understanding of EPA’s jurisdiction over these products, the public interest does not favor allowing continued sale of Berkey’s filters during the pendency of this litigation or resolution of the SSURO issued to Berkey International. That Plaintiffs or others may have sold these products for some time in violation of FIFRA is irrelevant. There is no estoppel against the government whereby if one violates the law for a certain period without detection, or even with

acquiescence, an enforcement action cannot later be brought. *See Utah Power & Light v. United States*, 243 U.S. 389, 408-09 (1917).

**2. Plaintiff has failed to show a lack of viable alternatives to Berkey Products.**

Plaintiff has failed to provide any evidence that other table-top water filters using carbon filters are inferior to Berkey Products. To be sure, there is much inflammatory rhetoric to this effect in Plaintiff's Motion and in its Complaint and supporting papers, and there are a number of improper lay opinions in the Shepherd Declaration that lack foundation or support, but these are not evidence on which the Court could base an injunction. Additionally, consumers have other alternatives in water filtration besides imitations of Berkey filters. For example, as noted in the New York Times article discussed above, there are pitcher and under-the-sink water filters that are smaller, cheaper, and easier to maintain. *See supra* p. 15.

Thus, Plaintiffs have failed to demonstrate that the public interest favors a preliminary injunction.

**Conclusion**

For the reasons set forth above, Plaintiffs' amended motion for a preliminary injunction should be denied.

Respectfully submitted,

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Certificate of Service

On April 17, 2024, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, District of Puerto Rico, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b).

/s/ Shari Howard  
Shari Howard  
Trial Attorney